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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,091	11/25/2003	Sebastiano Cavallaro	17357.01202US	4892

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EXAMINER

EMCH, GREGORY S

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

05/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/720,091

Applicant(s)

CAVALLARO ET AL.

Examiner

Gregory S. Emch

Art Unit

1649

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008 and 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,5-17 and 19-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 17 January 2008 has been entered.

Response to Amendment

Claims 1, 3 and 19-21 have been amended as requested in the amendment filed on 17 January 2008. Following the amendment, claims 1, 3, 5-17 and 19-21 are pending in the instant application.

Claims 5-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected subject matter, there being no allowable generic or linking claim.

Claims 1, 3 and 19-21 are under examination in the instant office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating

obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Ellsworth et al. (cited previously) in view of US 2001/0039261 to Finklestein.

The claims are directed to a method of enhancing memory, attentive cognition or learning in a human subject, comprising the step of administering Fibroblast Growth Factor 18 (FGF-18) to said human subject in an amount effective to enhance memory, attentive cognition or learning in said human subject.

The Ellsworth et al. reference teaches intravenous infusion of FGF-18 that reduced cerebral infarct volume and decreased deficits in reference and working memory, exploratory behavior and motor activity in rats with impaired cognitive performance after middle cerebral artery occlusion (thus enhancing memory, attentive cognition or learning, as in claims 1, 3 and 19-21). As stated previously, it was well known in the art that the hippocampus is involved in memory consolidation and working memory. Therefore, it was also well known to those of skill in the art that administration of a drug, in this case FGF-18, was necessarily increased in the brain (and therefore in the hippocampus) if improvement in cognition were achieved after treatment, as was found by Ellsworth, and as is required in claims 20 and 21. Therefore, absent evidence to the contrary, the Ellsworth et al. abstract appreciated the increase of FGF-18 in the brain and in the hippocampus since it teaches that FGF-18 enhanced memory, attentive cognition and learning (processes mediated by the hippocampus).

The difference between the experiments of the Ellsworth et al. reference and the claimed invention is that Ellsworth et al. do not disclose their treatment methods performed in human subjects. However, the concluding sentence of the reference states that the methods disclosed therein can be a therapy for the treatment of cognitive deficits after stroke in humans. Moreover, US 2001/0039261 to Finklestein teaches a method for treating a subject, including a human, who has suffered an injury to the central nervous system, such as an ischemic episode (e.g. stroke) by administering to the patient an FGF protein, including bFGF, aFGF and FGF-5 [006-008, 0037]. The reference teaches that treatment includes enhancing cognitive performance [0014], as in claim 19.

Upon reading the disclosure of the Ellsworth et al. reference, the skilled artisan would have recognized the desirability of developing improved methods for enhancing memory, attentive cognition and learning in humans, as in the claimed invention. As evidenced by the prior art, the skilled artisan would have known that human patients can be treated with an FGF family member to enhance cognitive performance (as taught by Finklestein) and that FGF-18 can be used in such methods (as taught by Ellsworth et al.). Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to improve Ellsworth et al.'s treatment methods in rats by practicing the invention in human subjects as taught by Finklestein et al. and expressly suggested by Ellsworth et al. Such would amount to a substitution of known equivalents to yield predictable results. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
16 May 2008

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646